referred to as "Keil"). Specifically, the Examiner contends that Wachter discloses a chitosan compound "within the instant claim" which is useful in cosmetic compositions. The Examiner also contends that Wachter discloses cosmetic compositions comprising the chitosans, carboxylic acids and ethanol in amounts of from 10-15%. The Examiner contends that Yu discloses topical compositions containing 2-hydroxycarboxylic acids, chitosan and 40% ethanol. The Examiner contends that Keil discloses a hair treatment composition containing chitosan, 2-pyrrolidone carboxylic acid and 40-50% ethanol.

The Examiner acknowledges that the cited references fail to teach compositions having the claimed amount of ethanol. The Examiner also acknowledges that the cited references fail to disclose the use of hydroxyisobutyric acid.

Nonetheless, the Examiner argues that it would have been obvious to one of ordinary skill in the art to "employ the particular amount (70-90% by weight) of ethanol in the cosmetic compositions", because "ethanol in 10-15% or 40-50% is known to be used in the cosmetic compositions comprising . . . chitosan and carboxylic acids . . . based on the prior art." (*See*, Paper No. 6, pp. 3-4 (*emphasis in original*)). The Examiner argues that one of ordinary skill in the art would have been motivated to optimize the amount of ethanol to 70-90% by weight.

Applicants strenuously, but respectfully, traverse the Examiner's rejection and the arguments and contentions set forth in support thereof, for the following reasons.

It is well-settled that in order to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

At the outset, Applicants would like to point out that the claimed invention is directed to cosmetic preparation comprising: (a) ethanol in an amount of from 70 to 90% by weight; and (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight. As set forth in the Specification, Applicants have surprisingly discovered that chitosan salts (*i.e.*, neutralization products of chitosans and the claimed carboxylic acids), exhibit significantly improved ethanol compatibility. The significantly improved ethanol compatibility of the chitosan salts allows for the production of predominantly alcohol-based formulations. (*See,* Applicants' Spec., p. 2, lines 8-10).

To begin with, Wachter does not teach cosmetic compositions including the claimed components. The citation proffered by the Examiner which allegedly teaches the inclusion of carboxylic acids, simply discloses that among many auxiliary surfactants which may be included in the taught cosmetic compositions are "ether carboxylic acids and salts thereof." (*See,* Paper No. 6, p. 2, Wacther, col. 4, line 61). The hardly qualifies as teaching neutralization products of chitosans and carboxylic acids, as claimed. Moreover, the only reference to ethanol in Wacther cited by the Examiner is a formulation example in Table 2 of the reference wherein a skin tonic is listed as containing 15% by weight of ethanol in combination with a chitosan compound, but without any carboxylic acid.

Yu discloses, in Example 2 thereof, a composition containing 5 grams of lactic acid in an aqueous/ethanol solution (less than 30% ethanol by weight) wherein 0.3 grams of a chitosan OR a polyquat is added as a gelling agent. There is no reference to chitosan salts. Even if chitosan were chosen as the gelling agent instead of the polyquat, the lactic acid exists as the acid, not the lactate (*i.e.*, neutralization product). Example 2 specifically teaches that the composition contains 5% 2-hydroxypropionic acid. Five grams of the acid in 100 mL of predominantly aqueous solution equates to 5% by weight.

Keil discloses hair treatment compositions. Three examples of the compositions contain a chitosan salt of pyrrolidone carboxylic acid and ethanol in amounts of from 40-50% by weight.

As the Examiner has acknowledged, none of the three references teaches the claimed amount of ethanol. The Examiner argues that the use of the claimed amount is simply a routine optimization. Applicants respectfully disagree with the Examiner's assessment. First, obviousness arguments based upon optimization are applicable only where the claimed subject matter is encompassed by the prior art. (*See*, M.P.E.P. §2144.05 II(A)). In the instant application, the claimed range of ethanol in the compositions according to the present invention is from 70 to 90% by weight. The cited references teach amounts of ethanol of 15%, 40% and 50% by weight. A range of from 70 to 90% by weight is not encompassed by the amounts of ethanol disclosed in the cited references. There is no teaching or suggestion to use greater amounts of ethanol. Second, "routine optimization" requires the identification of a result-effective variable. "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." (*See*, M.P.E.P. §2144.05 II(B) *citing In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)). Nothing in the cited references recognizes ethanol concentration as a result-effective variable.

Nothing in any of the cited references teaches or suggests a cosmetic preparation comprising: (a) ethanol in an amount of from 70 to 90% by weight; and (b) a neutralization product of a chitosan and an acid selected from the group consisting of lactic acid, pyrrolidone carboxylic acid, nicotinic acid, hydroxyisobutyric acid, hydroxyisovaleric acid and mixtures thereof, wherein the neutralization product is present in an amount of from 0.01 to 5% by weight. There is simply no teaching to use such large amounts. The largest amount taught is 50% by weight in a single example. Prior to Applicants' invention it was unknown that such large amounts of ethanol could be used with chitosan. Applicants discovered that the claimed neutralization products can be combined with large amounts of ethanol.

Moreover, none of the cited references contains any teaching or suggestion which would motivate one of ordinary skill in the art to modify the teachings of the prior art to utilize significantly greater amounts of ethanol than taught in the cited references. Motivation for modification must suggest a desirability to the modification. None of the references contains any such teaching.

Finally, given that neither reference teaches or suggests the claimed composition, and that neither reference suggests a modification necessary to arrive at the claimed invention, one of ordinary skill in the art would find no reasonable expectation of success in such a deviation based upon the teachings of the references.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the objection and rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

CLAUDIA PANZER, *et al.*

August 26, 2002
(Date)

By: _____

AARON R. ETTELMAN
Registration No. 42,516
COGNIS CORPORATION
2500 Renaissance Blvd., Suite 200
Gulph Mills, PA 19046
Telephone: (610) 278-4930
Facsimile: (215) 278-4971
E-Mail: AARON.ETTELMAN@COGNIS-US.COM

ARE:are